UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* ADAM HART, Plaintiff(s), v. MCKESSON CORPORATION, *et al.,* Defendants.	No.: 15-Civ-0903 (RA) (JC)

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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INTRODUCTION

In his opposition brief, Relator Adam Hart ("Hart") does not dispute that the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) advisory opinions use a substantial and independent value standard to evaluate whether analytic tools like Margin Analyzer ("MA") and Regimen Profiler ("RP") constitute remuneration to physicians. Nor is there any dispute that the *Suarez* and *Forney*[1] cases applied OIG advisory opinions in dismissing government-declined False Claims Act cases involving even more significant product support services. Nor is there any dispute that the MA and RP tools are very similar to information freely available on the Internet. There is no dispute, for example, that Memorial Sloan Kettering and other major institutions offer tools similar to MA and RP for free off the Internet.[2] The Relator does not challenge the authenticity of these Internet sites, nor that they can be accessed readily by anyone.

Instead, Relator asserts that the Court cannot consider the OIG opinions and the publicly available information, at least at this stage. But the publicly available information that allows tools similar to MA and RP to be downloaded in seconds are not somehow going to become "unpublic" after years of expensive discovery and the utilization of extensive judicial resources. Right now, these tools are public and show the MA and RP tools have no substantial and independent value. There is no bar for basic Internet citations from well-recognized institutions

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[1] *United States ex rel. Suarez v. AbbVie, Inc.*, No. 15-C-8928, 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019); *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568 (E.D. Pa. June 19, 2017).

[2] *See, e.g.*, Decl. of E. Solomon ISO Mot. to Dismiss ("Solomon Decl."), Ex. E, Drug Abacus, Drug Pricing Lab, https://drugpricinglab.org/tools/drug-abacus/ (last visited Sept. 13, 2020); Solomon Decl., Ex. H, Advance Practice Analytics from VitalSource GPO, Cardinal Health (2019), https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/cardinal-health-advanced-practice-analytics-brochure.pdf

to be considered by the Court — McKesson's opening brief cites several examples of courts using public information to dismiss cases under Rule 12 — and re-using these sources to make the same point at a later stage will not conserve the resources of the Court or the parties.

Relying on the OIG opinions or not, Relator cannot plausibly allege that analytic tools freely available on the Internet constitute illegal kickbacks. That is why the OIG has already declared that tools or other services that are publicly available do not implicate the AKS.[3] Calling these MA and RP tools kickbacks cannot alter the fundamental undisputed truth that (1) the MA and RP tools merely compare, mostly by spreadsheet, customer purchase price data with public reimbursement data; and (2) these kinds of comparators are easily found on the Internet (and can easily be mimicked by anyone with a spreadsheet).

On the Fed. R. Civ. P. 9(b) issue, Relator does not and cannot dispute that the Amended Complaint ("AC") fails to cite a *single* false claim, or even a single improper prescription caused by using the MA or RP tools. *See* Am. Compl. ¶ 22, ECF No. 16 [hereinafter "AC"] (citing "[o]n information and belief" that unnamed claims were submitted by unnamed customers on unnamed dates "in the above States"). The AC only identifies the MA spreadsheets for one specific customer, AC ¶ 53. Even if the Second Circuit does not require identification of significant claims detail, the core problems with the AC remain — beyond some general allegations for one customer, it fails to allege any detail whatsoever in the attenuated causal chain between access to the MA and RP tools and any eventual claims submitted by other unnamed entities at some later undetermined date. That is not sufficient under the standard in

[3] *See, e.g.*, OIG Adv. Op. No. 07-16, 2007 WL 6400843, at *3 (Dec. 5, 2007) (finding that home healthcare provider's free educational videos prior to surgery, did not implicate the AKS where "[s]imilar information content is available on the Internet and from other public sources without charge.")

United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc., which involved specific names and dates of false statements and false submissions to Medicare. 865 F.3d 71, 83–84 (2d Cir. 2017). This AC contains none of that detail. The Court can dismiss the AC on this basis alone and not even reach the other reasons for dismissal.

ARGUMENT

I. The Court Can Consider The Public Information Showing That The MA and RP Tools Had No Value Under the AKS

The Relator begins by asking the Court not to consider the OIG opinions, noting that "[e]very court that has considered these statutory and regulatory limitations has concluded correctly that OIG advisory opinions are not authority for anything." Opp'n at 10. This is obviously wrong. Numerous courts, including those in the Second Circuit, have considered OIG opinions in evaluating cases involving the AKS. *See, e.g.*, *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 552 (S.D.N.Y. 2018) (citing reasoning in multiple OIG opinions as to what constitutes remuneration).[4] Certainly the two cases cited in the opening brief, *Suarez* and *Forney*, considered some of the same OIG opinions that McKesson cited in its opening brief. The opposition brief creates barriers that Defendant never erected, such as interpreting Defendant's argument to seek an "uncodified safe harbor for kickbacks" (Opp'n at 9), or that a Court must consider OIG advisory opinions in all instances. Of course, the Court is not bound by these OIG opinions, and it is correct that OIG opinions formally apply only to the requesting party. But that has not stopped numerous other courts from applying OIG guidance in evaluating

[4] Relator's citation of *Alli-Balogun v. United States*, 281 F.3d 362, 370 (2d Cir. 2002), is misplaced. This opinion has nothing to do with OIG opinions, but rather concerns whether another Second Circuit opinion is binding on a statute of limitations issue. It is entirely irrelevant.

remuneration. And the consistent, common sense legal framework that OIG has applied is whether the item confers substantial and independent value.[5]

Whatever legal framework the Court uses, it is undisputed that tools with nearly identical information, comparing cost to reimbursement, are available for free on the Internet. Relator does not dispute nor question the authenticity of the following:

- The ASCO tools "allow physicians to compare reimbursement and profitability across competing medicines and treatment regimes."[6]
- The Memorial Sloan Kettering Cancer Center has developed a "drug pricing lab" called "Drug Abacus," which is a web-based tool that allows users to estimate the "value" of a drug by comparing the estimated price and reimbursement for the drug.[7]
- AmerisourceBergen offers a tool named the "Protocol Analyzer," which "helps practices better manage their oncology drug spend and optimize their reimbursements" by allowing practices to, among other things, "[a]nalyze economics of protocols" and "[c]ompare reimbursement by payer for clinically equivalent drugs."[8]

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[5] Relator misunderstands McKesson's argument on the "independent" prong. It is not whether the item is merely "related to" the customer relationship. It is whether the free item can have independent value outside that relationship, e.g., a computer that can be used for other office tasks. Here, the MA and RP tools have no value without actual McKesson purchase data — stripped of that, there is no comparison to reimbursement data. And the comparator calculators that form the essence of MA and RP are publicly available. That was not the case in any of the OIG opinions that Relator cites on pages 12–13 of its Opposition.

[6] *See* Solomon Decl., Ex. C, Am. Soc'y of Clinical Oncology, ASCO Value Framework Update: FAQs, https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-May-Updated-Value-Framework-FAQ.pdf

[7] *See* Solomon Decl., Ex. E, Drug Abacus, Drug Pricing Lab, https://drugpricinglab.org/tools/drug-abacus/ (last visited Sept. 13, 2020).

[8] Solomon Decl., Ex. J, Protocol Analyzer, ION Solutions, www.iononline.com/Solutions/Technology/Protocol-Analyzer (last visited Nov. 20, 2020).

- Cardinal Health's website describes several analytic tools for Oncology, including Regimen Analyzer, which is described as a "web-based tool that allows you to quickly compare financial implications and clinical outcomes by regimen, drug and disease", [c]ompare therapeutic class reimbursements", and "[u]ncover new opportunities to optimize your drug spend, identify all eligible reimbursements and ultimately decrease your patients' financial burden."[9]
- NantHealth offers, to anyone who registers on its website, a web-based tool that allows oncology practices to "[c]ompare treatment details including . . . costs" for "thousands of treatment regimens and clinical trials for all cancers and cancer subtypes."[10]

Instead, the Relator essentially interposes a hearsay objection to the Internet citations. Contrary to Relator's assertion, McKesson is not using the public sources — whose authenticity is not in dispute — to create some factual dispute, but merely as obvious public comparators to the challenged MA and RP tools. There is no reason the Court cannot consider these now, under Fed. R. Civ. P. 12, rather than waiting until significant discovery and judicial resources have been consumed, merely to confront the same Internet sources again. *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (determining that the district court could take judicial notice of the fact that press coverage, prior lawsuits, or regulatory filings contained certain information); *see also New Jersey Carpenters Health Fund v. Royal Bank of Scotland*

[9] Solomon Decl., Ex. I, Regimen Analyzer from VitalSource GPO, Cardinal Health (2019), https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/cardinal-health-regimen-analyzer-brochure.pdf.

[10] Solomon Decl., Ex. L, Eviti Advisor, NantHealth Eviti, https://connect.eviti.com/evitiadvisor/ (last visited Nov. 20, 2020).

Grp., PLC, 709 F.3d 109, 127 (2d Cir. 2013) (taking notice of two newspaper articles cited by defendants in a motion to dismiss).[11]

Nor are Relator's other arguments about value enough to overcome the obvious lack of value shown from MA and RP. The AC alleges in a conclusory fashion that the MA and RP tools made the practices more profitable, had "value for which practices would otherwise pay substantial sums of money" (AC ¶ 50), or "for which a physician practice might otherwise pay a practice-management consultant" (AC ¶ 101). But there is no example at all of a practice paying for these tools, or hiring some outside consultant to furnish these analytic calculators, even though the relator alleges he interacted with numerous physician practices for years. Certainly Relator cannot harmonize his conclusory allegations that unnamed customers paid for these tools when nearly identical tools are available for free.[12]

Nor is there merit to the argument that the MA and RP tools, even if lacking in value themselves, provided substantial value because they allowed the practices to increase revenue.

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[11] Relator's only challenge to the substance of the Internet citations is the assertion that they are aimed at patients and do not assist clinicians in calculating potential profits. Opp'n at 19 n.9. That is not the case. These tools on the Internet are squarely aimed at clinicians and they do assist, for example, oncologists to "assess the relative value of cancer treatment regimens that have been studied head-to-head in clinical trials." *See* Solomon Decl., Ex. C (ASCO tool). And the argument that these Internet tools are only "demos" for prospective customers is illusory -- the tools on the Internet omit only the customer's actual purchase data, which anyone can complete. The point is that these public tools do the same thing as MA and RP — show charts of how to compare acquisition cost with publicly available reimbursement data.

[12] Relator cites the AC's allegation "that another division [of McKesson] sold access to them, confirming their substantial value[,]" but there is no allegation that MA and RP were sold as individual products. The AC itself concedes that the U.S. Oncology Network has an entirely different business model in which the network "collects from its affiliated physician practices a management fee set as a percentage of either a practice's revenues or earnings and in exchange "provides those practices a variety of tools and services[,]" including MA and RP. (AC at ¶¶ 105-06). That is why Relator excluded the US Oncology practices from this case. The AC does not and cannot show that MA and RP were separately priced or had any value as part of the overall management fee.

The value is in the tools themselves, not what value can be created from them. If the reverse was true, then providing a 99 cent calculator could be worth millions because someone can use the calculator to crunch numbers and realize more revenue.[13]

In the end, no amount of speculation about value can disguise the fact that MA and RP are simple calculator tools that compare acquisition costs with public reimbursement data for various medicines or treatment regimens. That is why these spreadsheet models are so freely available on the internet. Like the *Forney* and *Suarez* cases, in which the challenged support service was not even publicly available, this Court can dismiss now at this stage because MA and RP do not provide "illegal remuneration with independent value." *Forney*, 2017 WL 2653568, at *4.[14]

II. The Court Should Dismiss the AC Under Rule 9(b) Because Identifying One Customer Who Received MA and RP Is Insufficient.

Relator asserts that the AC satisfies Rule 9(b) because it attaches several MAs provided to a specific customer, Summit Cancer Care. From that one assertion, and from that one customer, Relator asks the Court to fill in the details on not only the claims submitted by Summit, none of which is identified, but for *all other unidentified customers around the country*.

[13] For this reason, OIG treats drug samples given to physicians as nominal value, even though these drug samples that physicians then dispense to patients can create additional income and value to the physician. *See* OIG, A Roadmap for New Physicians: Fraud and Abuse, available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf (last visited Nov. 20, 2020) (sample is considered an item of nominal value, even if the nominal value item ultimately has some impact on the physician's ability to increase revenue).

[14] Relator asserts that Forney filed a new complaint after dismissal, but Defendant addressed this in its opening brief, observing that the new complaint contained significant new detail that Medtronic employees assisted with clerical tasks, such as data entry and scheduling, Forney, Second Am. Compl. ¶¶ 32, 33, 36, 40, and performed hospital functions that would otherwise be provided by a clinical technician, *id.* ¶¶ 26, 36. There is no such detail here. And even with this detail, the court was still "reluctant" to let the case proceed.

The identification of MAs for one customer, Relator asserts, "raises a strong inference" that "thousands of false claims" were submitted somewhere, sometime, around the country. That stretches *Chorche*s beyond its breaking point. For one, *Chorches* involved a plaintiff who provided specific names and dates of false representations and submissions to Medicare.[15] Second, the alleged "nationwide scheme" alleged in this case, which is supposed to forgive the lack of claims detail, itself lacks too many elements. The AC still fails to allege how any physician made a prescription decision — even just one — based on use of MA or RP, much less which medicine was involved, or whether the unnamed medicine resulted in higher costs. Asking the Court to complete the story between receipt of MA and RP and any eventual and unspecified claims is too much of a leap of faith under *Chorches*, particularly when the Relator claims to be an "insider" with access to detailed information. *See* AC ¶ 14.

Even if the allegations regarding Summit could be considered sufficient — which they are not — the Court should dismiss Relator's claims concerning RP as to all customers and as to RP and MA as to all customers other than Summit, as the AC offers no specific allegations for any customer other than Summit, and even those allegations are focused on MA. If the Court does not take that approach, at a minimum the Court should limit the case for MA to the customers identified cited in paragraph 53 and limit the case for RP to the customers identified cited in paragraph 101, customers which are all in one state despite Relator's assertion of a nationwide scheme. *See United States ex rel. Judd v. Quest Diagnostics, Inc.*, 638 F. App'x 162, 168–69 (3d Cir. 2015) (affirming dismissal of a relator's FCA claims for failure to satisfy Rule 9(b) as to all healthcare providers other than a single provider specified in the complaint, where

[15] *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response*, Inc., 865 F.3d 71, 82 (2d Cir. 2017).

the court determined that "the paragraphs of [Relator's] Amended Complaint that he argues contain specific allegations have nothing to do with [Defendant's] dealings with" any other medical providers); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) (affirming dismissal for all claims those concerning eight customers for which the complaint described "information as to the dates and amounts of the false claims filed by these providers with the Medicare program.")).

III. The AC Must Be Dismissed Because It Does Not Allege A Specific Intent to Violate the Law

Relator is incorrect that the 2010 amendments to the AKS eliminated the requirement to plead a specific intent offense. The AKS may not require that an individual know the prohibited conduct specifically violated the AKS, but Relator still must show that the defendant acted "knowingly" and "willfully," 42 U.S.C. § 1320a–7b(b), and that means with an intent to do something unlawful. *See United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. CV 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); *see also Bryan v. United States*, 524 U.S. 184, 191 (1998) ("As a general matter . . . a "willful" act is one undertaken with a "bad purpose."). Numerous cases after 2010 dealing with post-2010 facts make this clear. *See, e.g.*, *United States v. Shvets*, 631 F. App'x 91, 94 (3d Cir. 2015) (upholding AKS jury instruction that defendant must have "acted with a purpose to disobey and disregard the law").

Here, as in *Forney*, there is no allegation that "any [McKesson] employee knew that providing free services" violated the law. *See Forney*, 2017 WL 2653568, at *5 ("Knowledge in this context means actual knowledge that the alleged false claims were fraudulent, deliberate ignorance as to the claims' fraudulent nature, or reckless disregard of the claims' truth or falsity."; "Forney has not, however, alleged that any Medtronic employee knew that providing free services violated the AKS or that the providers Medtronic serviced would submit false

claims."). Relator makes the conclusory allegation that "McKesson intentionally decided to employ these illegal kickbacks," but merely saying a company intentionally offered a program that now is alleged to be a kickback is insufficient. *See id.* at *5 (finding AKS scienter requirement not satisfied where relator alleged that "Medtronic induced physicians and others with purchasing power to select Medtronic devices" (internal quotation marks omitted)). There is no allegation that a single employee, much less McKesson, knew or believe that providing MA and RP was wrong, even though Relator claims to have worked closely with McKesson personnel for years. The AC does not and cannot allege that a single employee of McKesson knew or believed that providing MA and RP was unlawful. That standard is still required. And the opposition brief cannot explain how McKesson, or even a single individual, knew its conduct was wrong given that it explained these tools on its website, Defs.' Br. p. 18 n.29, just as many other organizations publicly discussed their own analytic calculators, Defs.' Br. 15–17.

CONCLUSION

For the foregoing reasons, the Court should dismiss the AC with prejudice.

Dated: November 23, 2020

Respectfully submitted,

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